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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,503	09/13/2001	Robert-Peter Klein	512100-2022	6117
20999	7590	02/25/2004		
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 02/25/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/936,503

Applicant(s)

KLEIN ET AL.

Examiner

Micah-Paul Young

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 and 9-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

**Acknowledgment of Papers Received:** Request for Continued Examination 11/24/03

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 7, 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures and teachings of Hoffmann (USPN 5,820,876 hereafter '876) in view of Nichols (USPN 4,804,541) and Phillips (USPN 4,732,153 hereafter '153).

4. '876 et al teaches a TTS with a backing layer, drug depot, and matrix, which encompasses the drug depot. The TTS further comprises a pressure sensitive adhesive, which adheres to the skin. The drugs and active agents delivered by the TTS ranges from nicotine to sexual hormone like progesterone and thymoleptics like scopolamine (hydrobromide) (col. 3, lin. 23 – 67; Fig. 1 – 3; col. 5, lin. 24 – col. 6, lin. 22). The reference however does not disclose a paper support material for the matrix, however the reference does disclose a fibrous cellulosic material, which suggests the presence of a paper-like substance.

'541 et al teaches a TTS with a backing material impermeable to the active agents. The TTS further comprises a pressure sensitive adhesive component that affixes to the skin and a matrix component that contains the active agents. The matrix material is can be made of

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absorbent paper. The active agent of the invention is the sexual hormone estradiol (col. 2, lin. 15 – 29; lin. 57 – 65; col. 3, lin. 3 – 11). The paper does not disclose a rigidity or weight.

‘153 discloses a transdermal device where the matrix is a heavy weight absorbent filter paper (example 1).

With regard to claims 10 – 12, the specific weight of the paper used as a support for the active agent would be determined through routine experimentation by one of ordinary skill in the art. A skilled artisan would be able to determine the optimal weight of paper in order to maximize the absorption of the active agent and the delivery of the agents. Regarding claims 13 and 1, a skilled artisan would be able to modify the amount of the active agent applied to the substrate. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various transdermal compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

A skilled artisan would be able to follow the suggestions of ‘876 to include the absorbent paper of ‘541 in order to provide a proper support for the TTS. The artisan would have seen from ‘153 that papers could be of heavy weight and absorbent, providing rigidity and an absorbent quality as well. A skilled artisan would have been motivated to substitute the matrix

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of '541 into the structure of '876 in order to improve to improve the transmission of the active agent, specifically estradiol. It would have been obvious to combine these teachings since they both deliver sexual hormones transdermally. It would have been obvious to combine these teachings as such with an expected result of a TTS device with a paper-supported matrix that delivers estradiol.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 7-15 have been considered but are moot in view of the new ground(s) of rejection. However, the examiner would like to address the remarks regarding the Nichols reference. Applicant argues that the claim limitation "support paper" implies rigidity to the TTS. It is the position of the examiner that "support" does not imply rigidity, yet a description of a component. Support material can be flexible, and absorbent as seen in bandages, and in the '153 reference (example 1). The '153 reference discloses a heavy weight absorbent paper material used in a transdermal device. Further the claims do not exclude that the paper cannot be absorbent, only tat it provides support for the drug depot. Again if rigidity of the TTS is a defining feature of the instant invention, the applicant is invited to include such limitations barring they are properly supported by the specification.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

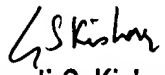
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MP Young

Micah-Paul Young  
Examiner  
Art Unit 1615

  
Gollamudi S. Kishore, PhD  
Primary Examiner, ✓  
Group 1600